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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,229

08/30/2005

Ilaria Capua

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25226 7590 02/17/2009  
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EXAMINER

HILL, MYRON G

ART UNIT

PAPER NUMBER

1648

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DELIVERY MODE

02/17/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/511,229	<b>Applicant(s)</b> CAPUA ET AL.	
	<b>Examiner</b> MYRON G. HILL	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-17 is/are pending in the application.
- 4a) Of the above claim(s) 4, 12 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-11, 15 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This action is in response to the papers filed 11/13/08.

Claims 1-4, 6-11, 15, and 17 are under consideration.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6, 10, 11, 15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Capua *et al.* (Veterinary Record 2000, Vol 147, No 26 page 751 from IDS).

Applicant has amended claim 1 to recite the biological specimen is from an animal that has been subject to vaccination by means of a heterologous vaccine characterized by different Na subtype.

Applicant argues that the examiner states that Capua et al does not teach specific assays, that Capua et al. does not teach Na Ab bound to antigen, that Capua et al. teach a different assay type, and that the conventional test was a NI test not the assay claimed.

Applicant's arguments have been fully considered and not found persuasive.

The new limitation is met in Capua et al. (middle paragraph, page 751) which teaches use of homologous H7 and heterologous N3 to differentiate from influenza H7N1 by means of an *ad hoc* diagnostic assay that detects specific antibodies to N1 versus N3. While Capua et al. does not specifically say biological fluid, the only source of antibodies from an animal is from biological fluid because antibodies are found in the serum.

While Capua et al. does not disclose specific assays or antigen bound to antibody, Capua et al. teach detecting antibody to different N subtypes. This clearly anticipates having antigen and antibody bound to each other and the use of antigen in a method to detect antibodies.

Applicant tries to differentiate the method of Capua et al. from the instant claims by arguing (page 6 of response, middle, paragraph beginning Thus, Capua focuses...) the methods detect different things. Capua et al. diagnoses influenza infection in the assay taught by being able to differentiate *infected* birds from vaccinated birds. Capua et al. do not teach specific method of using a ELISA or dip stick for field use but Capua et al. teach detecting specific antibodies.

Thus, the claims are anticipated by Capua *et al.*

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims are 1 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Capua *et al.* (Veterinary Record 2000, Vol 147, No 26 page 751) and Van de Perre *et al.* (J Clinical Micro. 1988 Vol 26, pages 552-556).

Applicant argues that the references alone or in combination do not make the invention obvious and also refers to *KSR*. Applicant also argues about vaccinating birds and distinguishing vaccinated birds from infected birds.

Applicants argument have been fully considered and not found persuasive.

As discussed above, the vaccine and detection needs are taught in Capua *et al.* and teaches that the assay will be detecting Na from vaccinated birds versus infected birds by means of antibody detection. Van de Perre *et al.* is used to show what antibody tests were known and used in the art.

Thus, the rejection is maintained.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MYRON G. HILL whose telephone number is (571)272-0901. The examiner can normally be reached on M,W,F, and flex.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/M. G. H./

Examiner, Art Unit 1648

/Bruce Campell/

Supervisory Patent Examiner, Art Unit 1648